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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,400	06/27/2003	Michael J. Pugia	017191.0042 (MSA-3453)	7945
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SIEMENS CORPORATION INTELLECTUAL PROPERTY DEPARTMENT 170 WOOD AVENUE SOUTH ISELIN, NJ 08830			EXAMINER	
			SINES, BRIAN J	
			ART UNIT	PAPER NUMBER
			1797	
			MAIL DATE	DELIVERY MODE
			08/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/608,400	Applicant(s) PUGIA ET AL.
	Examiner Brian J. Sines	Art Unit 1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 24 April 2008.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 3-8,11-16 and 28-38 is/are pending in the application.

4a) Of the above claim(s) 11-16,28-32,34,35,37 and 38 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 3-8,33 and 36 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application

6) Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I comprising claims 3 – 8, 33 and 36 in the reply filed on 4/24/2008 is acknowledged. The traversal is on the ground(s) that both of the inventions are not independent and distinct and that there would be no serious burden placed on the Examiner during examination. This is not found persuasive because, as indicated in the restriction requirement mailed 3/21/2008, the two inventions are indeed independent and distinct and have been classified accordingly. The microfluidic devices in the independent claims of each group recite different structural features and/or different combinations of features and therefore also differ in claim scope. Furthermore, the primary classification of claimed subject matter is merely one indication of the burdensome nature of the search requirements and a serious burden on the Examiner may also be shown by appropriate explanation of the field of search (see MPEP § 803). The restriction requirement merely refers to the primary classification for the inventions, not the complete scope of the prior art search in additional art class and subclass classifications that would be required in determining patentability. Clearly, since the different groups comprising each of the inventions comprise different features and/or different combinations of features, different searches and patentability determination issues are involved in the examination of each invention. The requirement is still deemed proper and is therefore made FINAL.

Claims 11 – 16, 28 – 32, 34, 35, 37 and 38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Response to Arguments

The declaration under 37 C.F.R. 1.132 filed 12/14/2007 was reviewed by the Examiner. However, Applicant's arguments with respect to the present claims have been considered but are 5 moot in view of the new ground(s) of rejection. The Applicant is advised that the evidence presented regarding enablement must not be directed to information that should have been in the specification as filed. The cited prior art in the new rejection below teaches all of the positively recited structure of the claimed apparatus. If the prior art structure is capable of performing the intended use, then it meets the claim. Apparatus claims must be structurally distinguishable from 10 the prior art in terms of structure, not function. The manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim (see MPEP § 2114 & § 2173.05(g)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all 15 obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the 20 manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

25

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 3, 5, 6, 33 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over
5 Buechler (U.S. Pat. No. 6,113,855) in view of Hillman et al. (U.S. Pat. No. 4,756,884).

Regarding claims 5, 6, 33 and 36, Buechler teaches a microfluidic device structure comprising: an inlet port or entry 12; an enclosed capillary passageway 14 in fluid communication with the inlet port 12; an enclosed inlet chamber or well (e.g., distal region 16) having a substrate surface comprising an array of post structures (i.e., capillarity-inducing
10 structures 30) that is also positioned adjacent the substrate; and a vent structure (i.e., escape port 18) (see col. 5, line 21 – col. 7, line 43; figures 1 & 4). As shown in figure 1, the enclosed inlet chamber 16 is in fluid communication at one side or end side thereof with the enclosed capillary passageway 14. In addition, as shown in figure 1, the vent passageway 18 is positioned at a top side of the enclosed inlet chamber opposite the entry of the capillary passageway 14 into the
15 enclosed inlet chamber 16. The device further comprises a lid 20 that further defines a top surface of well 16 (see figure 3).

Buechler does not specifically teach a reagent deposited on an adsorbent substrate, wherein the substrate is positioned adjacent to the uniform array of posts.

The Applicant is advised that the Supreme Court recently clarified that a claim can be
20 proved obvious merely by showing that the combination of known elements was obvious to try. In this regard, the Supreme Court explained that, “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has a good reason to pursue the known options within his or her technical grasp.” An obviousness determination is not the result of a rigid formula disassociated

from the consideration of the facts of the case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. The combination of familiar elements is likely to be obvious when it does no more than yield predictable results. Furthermore, the simple substitution of one known element for another is

5 likely to be obvious when predictable results are achieved. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007) (see MPEP § 2143).

In that regard, Buechler does teach the incorporation of surface bound reagents, e.g., antibodies, on a solid phase within region 16 containing the assay volume and adjacent capillarity-inducing structures 30 (see, e.g., col. 4, lines 42 – 67; col. 5, lines 36 – 67; figures 1

10 – 4).

The use of reagent-containing absorbent substrates with similar testing devices is well known in the art. For example, Hillman et al. teaches a similar testing device that uses capillary flow and surface bound or coated reagents. Hillman also teaches that the reagents can be provided on an absorbent substrate comprising a sponge, gel, membrane or filter paper within the reaction unit of the disclosed device (see, e.g., col. 15, line 66 – col. 17, line 30; in particular, col. 16, lines 55 – 61). Consequently, as shown by Hillman, a person of ordinary skill in the art would have recognized the predictable use of reagent-containing absorbent substrates with similar testing devices using capillary flow in facilitating sample fluid flow control and assaying. Therefore, it would have been obvious to a person of ordinary skill in the art to substitute and incorporate a reagent-containing absorbent substrate with the disclosed microfluidic device in order to facilitate effective sample fluid flow control and subsequent testing.

Regarding claim 3, Buechler teaches the incorporation of an array of posts comprising more than one row or column of posts 30 (see figures 3, 4, 5B and 6B).

Regarding claims 5 and 6, these claim limitations would have been obvious to a person of ordinary skill in the art upon incorporation of the reagent-containing absorbent substrate with the 5 device structure taught by Buechler. With respect to claim 5, the array of posts could be positioned above or before the absorbent substrate within well 16 so that a uniform flow of sample fluid would be established before contacting the reagent-containing absorbent substrate for analysis. With respect to claim 6, upon incorporation of the absorbent substrate, it would have been obvious to a person of ordinary skill in the art to incorporate the absorbent substrate to 10 contact the array of posts so that a uniform distribution of sample fluid would result in contacting the reagent-containing absorbent substrate.

Regarding claim 36, upon incorporation of the absorbent substrate, it would have been obvious to a person of ordinary skill in the art that the array of posts 30 could be positioned between entry 12 and the absorbent substrate so that a uniform flow of sample fluid would 15 contact the reagent-containing absorbent substrate.

2. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler and Hillman et al., and further in view of Peters (U.S. Pat. No. 6,296,126).

Regarding claim 4, Buechler is silent to the specific teaching of incorporating wedge-shaped cut-out structures with the disclosed microfluidic device.

20 However, as shown in figure 3b, Peters does teach the incorporation of wedge-shaped cut-out structures (post or columnar projection 9 having wedge-shaped cut-outs 1) within a

microfluidic apparatus for facilitating effective fluid control within a microfluidic device (see col. 1, line 10 – col. 6, line 67; figures 1a, 3b & 4).

The combination of familiar elements is likely to be obvious when it does no more than yield predictable results. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 5 1385, 1397 (2007) (see MPEP § 2143).

Therefore, as evidenced by Peters, a person of ordinary skill in the art would have recognized the suitability and predictable incorporation and use of wedge-shaped cut-out structures within a microfluidic apparatus for the intended purpose of facilitating effective fluid control (see also MPEP § 2144.07). Consequently, a person of ordinary skill in the art would 10 accordingly have had a reasonable expectation of success of incorporating the use of these wedge-shaped cut-out structures within the disclosed microfluidic apparatus for facilitating effective fluid control (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of wedge-shaped cut-out structures as claimed with the disclosed microfluidic device in order to provide an effective for effective 15 sample fluid control within the microfluidic apparatus.

3. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beuchler and Hillman, and further in view of Columbus (U.S. Pat. No. 4,233,029).

Regarding claim 7, as shown in figure 7a, Columbus further teaches the incorporation of ramp structures comprising a plateau surface structure configuration (e.g., truncated ridges 46) 20 within a similar testing the device (see, e.g., col. 8, lines 1 – 51).

The combination of familiar elements is likely to be obvious when it does no more than yield predictable results. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007) (see MPEP § 2143).

Therefore, it would have been obvious to a person of ordinary skill in the art to

5 incorporate a weir structure as claimed for facilitating effective sample fluid flow with the disclosed microfluidic device.

Regarding claim 8, Beuchler does not specifically teach the incorporation of at least one groove structure extending across the inlet chamber 16.

10 Columbus teaches the use of groove structures (e.g., 42 & 44) for facilitating uniform fluid flow within microfluidic devices (see, e.g., col. 5, lines 1 – 55; figure 3).

The combination of familiar elements is likely to be obvious when it does no more than yield predictable results. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007) (see MPEP § 2143).

15 Hence, as shown by Columbus, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating the use of a groove structure with an analytical microfluidic device for facilitating uniform sample fluid introduction into the device for processing and analysis. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a groove structure as claimed with the disclosed microfluidic device in order to facilitate effective uniform sample fluid distribution within the
20 device.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE
5 MONTHS from the mailing date of this action. In the event a first reply is filed within TWO
MONTHS of the mailing date of this final action and the advisory action is not mailed until after
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,
10 however, will the statutory period for reply expire later than SIX MONTHS from the mailing
date of this final action.

Any inquiry concerning this communication or earlier communications from the
examiner should be directed to Brian J. Sines whose telephone number is (571) 272-1263. The
examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

15 If attempts to reach the examiner by telephone are unsuccessful, the examiner's
supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the
organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian J. Sines
Primary Examiner
Art Unit 1797

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